



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,281	10/16/2003	Naomi L. Nakao	G30-014	8977
7590	06/14/2005		EXAMINER	
R. Neil Sudol 714 Colorado Avenue Bridgeport, CO 06605-1601			AHMED, AAMER S	
			ART UNIT	PAPER NUMBER
			3763	
DATE MAILED: 06/14/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,281

Applicant(s)

NAKAO, NAOMI L.

Examiner

Aamer S. Ahmed

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities: Page 11 Line 19, the phrase "fully" is misspelled.

Appropriate correction is required.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference signs mentioned in the description: 21 Page 8 Line 12; 16 Page 9 Line 1. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be

Art Unit: 3763

labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10- 13, 16-23, 25- 27, 30, 31, 32, 33, 34, 35, 36, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill ('961).

As to Claim 1, Hill describes a medical device comprising a tubular member, (16) an elongate member (24) disposed at least partially inside said tubular member; and a resilient loop (32) of a first size attached to one end of said elongate member, said loop

Art Unit: 3763

including a bend (22) on a side of said loop opposite said elongate member, said loop further including two loop sections each extending between said elongate member and said bend, with a notch disposed at a mouth opening of said tubular member (14). (See Figures 1 and 4b).

As to Claim 2, Hill discloses that the instrument described above in reference to claim 1 wherein each of said loop sections is formed with a respective notch or dent (30) for enabling use of said loop in said second size upon a positioning of said loop relative to said tubular member so that said notches or dents are disposed at said mouth opening of said tubular member. (See Figure 4b).

As to claim 3, Hill teaches that the instrument described above in reference to claim 2 above wherein the notches or dents are disposed at substantially the same first distance from said one end of said elongate member and substantially the same second distance from said bend. (See Figure 4b)

As to Claim 4, Hill discloses, the instrument defined in claim 3 wherein said first distance is approximately 30% to approximately 40% of the sum of said first distance and said second distance. (See Figure 4b).

Thus, Hill reasonably appears to teach and disclose every element of claims 1-4.

As to Claims 5-7 and 10, Hill describes that the instrument disclosed above in reference to claim 4 wherein each of said notches or dents includes a pair of linear segments (12) connected to one another by an arcuate bend, (30 and 32) said segments being disposed at an angle of approximately 80 degrees to approximately 120 degrees relative to one another; the said bend is part of a nose projection of said

loop, each of said loop sections including a respective bend disposed between said nose projection and the respective one of said notches or dents; the respective bends in said loop sections are located at approximately the same distance from said nose projection so that said loop is provided with an enlarged distal end portion and; the notch of each one of said loop sections extends toward the other loop section. (See Figure 4b).

Thus, Hill reasonably appears to teach and disclose every element of claims 5-7 and 10.

As to Claims 11-13, Hill teaches that the instrument taught above in reference to claim 2 wherein said loop lies in a single plane, said notches or dents being located in said plane; the loop has a relaxed configuration wherein the loop sections are spaced from one another by a loop width, each of said notches or dents having a width dimension measured in a direction from the respective loop section towards the other loop section, said width dimension being no larger than approximately fifteen percent of said loop width; and the notches (30) each have a V shape. (See figure 4b).

As to claim 16-23, Hill discloses the instrument as taught above in reference to claim 1 wherein said one of said loop sections is curved in a fully expanded configuration of said loop, the other of said loop sections being straight in said fully expanded configuration of said loop; (32) the notch is one of a plurality of notches formed along said one of said loop sections; the notch is located at a first distance from said one end of said elongate member and a second distance from said bend, said first distance being approximately 30% to approximately 40% of the sum of said first

distance and said second distance; the notch or dent includes a pair of linear segments connected to one another by an arcuate bend, said segments being disposed at an angle of approximately 80 degrees to approximately 120 degrees relative to one another; the bend is a first bend, said one of said loop sections including a second bend disposed between said first bend and said notch or dent, said second bend being concave towards the other of said loop sections. Moreover, Hill discloses, that the loop lies in a single plane, said notch or dent being located in said plane; the loop has a relaxed configuration wherein said loop sections are spaced from one another by a loop width, said notch or dent having a width dimension measured in a direction from said one of said loop sections towards the other of said loop sections, said width dimension being no larger than approximately fifteen percent of said loop width; the notch has a V shape. (See Figures 1 and 4b).

Thus, Hill reasonably appears to teach and disclose every element of claims 16-23.

As to claims 25-27, Hill teaches a medical instrument comprising: a tubular member (16); an elongate member (24) disposed at least partially inside said tubular member; and a resilient loop of a first size attached to one end of said elongate member, said loop including a nose projection (22) on a side of said loop opposite said elongate member, said loop further including two loop sections each extending between said elongate member and said nose projection, each of said loop sections being formed with at least one respective notch or dent (30 and 32); the notches are disposed at substantially the same first distance from said one end of said elongate member and substantially the same second distance from said nose projection; and wherein first

distance is approximately 30% to approximately 40% of the sum of said first distance and said second distance. (See Figures 1 and 4b).

Thus, Hill reasonably appears to teach and disclose every element of claims 25-27.

As to Claims 30-36, Hill describes, the instrument disclosed above in reference to claim 25 wherein the notch or dent in a given one of said loop sections is one of a plurality of notches or dents formed along said given one of said loop sections; 31; each of said notches or dents includes a pair of linear segments connected to one another by an arcuate bend said segments being disposed at an angle of approximately 80 degrees to approximately 120 degrees relative to one another; the bends in said loop sections are located at approximately the same distance from said nose projection so that said loop is provided with an enlarged distal end portion; the notch or dent of each one of said loop sections extends toward the other loop section; the loop lies in a single plane, said notches being located in said plane; the loop has a relaxed configuration wherein said loop sections are spaced from one another by a loop width, each of said notches having a width dimension measured in a direction from the respective loop section towards the other loop section, said width dimension being no larger than approximately fifteen percent of said loop width and; the notches or dents each have a V shape. (See Figures 1 and 4b).

Thus, Hill reasonably appears to teach and disclose every element of claims 30-36.

As to Claim 37, Hill describes a medical instrument comprising a snare provided with provided with at least one notch for enabling use of said snare (32) in any of a plurality of effective sizes. (See Figure 4b).

Thus, Hill reasonably appears to teach and disclose every element of claim 37.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8, 9, 14, 15, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('961) taken in view of Nakao et al ('187). Hill discloses the looped medical device as described above in reference to Claims 1 and 7. Furthermore Hill discloses that the loop be made of an electrically conductive material. (See Column 3). Hill fails to disclose a pouch attached to said loop.

Nakao et al ('187) does disclose a pouch (24) slidably attached to the loop. (See Figure 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the looped medical device of Hill by adding the pouch as taught by Nakao et al ('187) in order to capture the severed tissue.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('961) taken in view of Nakao et al ('187). Hill discloses the looped medical device as described above in reference to Claim 25. Furthermore Hill discloses that the loop be made of an electrically conductive material. (See Column 3). Hill fails to disclose a pouch attached to said loop.

Nakao et al ('187) does disclose a pouch slidably attached to the loop. (See Figure 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the looped medical device of Hill by adding the pouch as taught by Nakao et al ('187) in order to capture the severed tissue.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill ('961) taken in view of Nakao et al ('187). Hill discloses the looped medical device comprising a tubular member (16), an elongate member (24), disposed at least partially inside said tubular member and a resilient loop of a first size attached to one end of said elongate member, said loop including a bend (22) on a side of said loop opposite said elongate member, said loop further including two loop sections each extending between

said elongate member and said bend, at least one of said loop sections being formed with at least one respective notch or dent. (See Figures 1, 3b and 4b).

Hill does not disclose the method of inserting an endoscope with a biopsy channel into a patient, inserting the instrument through a biopsy channel, ejecting the loop and encircling tissue of different sizes.

Nakao ('187) does disclose a method of inserting an endoscope into a patient, said endoscope having a biopsy channel; inserting said instrument through said biopsy channel, said loop being disposed in said tubular member during the inserting of said instrument, after the inserting of said endoscope and the inserting of said instrument, pushing said elongate member to eject said loop at least partially from said tubular member at a distal end of said endoscope; using the at least partially ejected loop to encircle a first desired tissue mass of a first size inside the patient, said loop being substantially entirely outside of said tubular member during the using of said loop; and using the at least partially ejected loop to encircle a second desired tissue mass of a second size inside the patient, said second size being substantially smaller than said first size, said loop notch or dent being initially disposed at a mouth opening of said tubular member during the using of said loop to encircle said second desired tissue mass. (See Columns 15-17).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 3763

U.S. Pat. No. 6015415	Avellanet
U.S. Pat. No. 5263493	Avitall
U.S. Pat. No. 5788710	Bates et al.
U.S. Pat. No. 6254601	Burbank et al.
U.S. Pat. No. 6730097	Dennis
U.S. Pat. No. 6551327	Dhindsa
U.S. Pat. No. 6602204	Dubrul et al.
U.S. Pub. No. 20010009985	Durgin et al.
U.S. Pub. No. 20030212389	Durgin et al.
U.S. Pat. No. 6221039	Durgin et al.
U.S. Pat. No. 6610056	Durgin et al.
U.S. Pat. No. 5334210	Gianturco
U.S. Pat. No. 5957923	Hahnen et al.
U.S. Pat. No. 5957884	Hooven
U.S. Pat. No. 6423085	Murayama et al.
U.S. Pat. No. 5782840	Nakao.
U.S. Pat. No. 5190542	Nakao et al
U.S. Pat. No. 5201740	Nakao et al.
U.S. Pat. No. 5997547	Nakao et al.
U.S. Pat. No. 5741271	Nakao et al.
U.S. Pat. No. 5486182	Nakao et al.
U.S. Pat. No. 5336227	Nakao et al.

U.S. Pat. No. 6190382	Ormsby et al.
U.S. Pat. No. 6663625	Ormsby et al.
U.S. Pat. No. 6423060	Ouchi
U.S. Pat. No. 5735289	Pfeffer et al.
U.S. Pat. No. 6017339	Sadamasa
U.S. Pat. No. 6814739	Secrest et al.
U.S. Pat. No. 5542432	Slater et al.
U.S. Pat. No. 6786905	Swanson et al.
U.S. Pat. No. 6152920	Thompson et al.
U.S. Pat. No. 6425914	Wallace et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

aa



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
EBC CENTER 3700